

Package leaflet: Information for the patient

Diclofenac Diethylamine  
2.32% w/w Gel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Diclofenac Diethylamine 2.32% w/w Gel is and what it is used for

Diclofenac Diethylamine 2.32 % w/w Gel contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin.

This medicine is used to relieve pain and reduce inflammation and swelling in a number of painful conditions affecting the joints and muscles. Diclofenac Diethylamine 2.32 % w/w Gel can be used to treat:

- muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), relieving pain and helping recovery back to normal function
- tendonitis (e.g. tennis elbow), swelling around elbow or knee
- mild arthritis (symptoms of mild arthritis include joint pain at rest, joint pain on movement, joint swelling or stiffness (after sleep or long rest)).

2. What you need to know before you use Diclofenac Diethylamine 2.32% w/w Gel:

DO NOT use Diclofenac Diethylamine Gel if you:

- are allergic (hypersensitive) to diclofenac or other medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin (a substance also used to prevent blood clotting), or any of the other ingredients of this medicine (see section 6 and end of section 2). If you are not sure, ask your doctor or pharmacist. Symptoms of an allergic reaction may include: wheezing or shortness of breath (asthma); skin rash with blisters or hives; swelling of the face or tongue; runny nose.
- have severe joint pain of recent onset that is not related to an injury or period of overuse
- feel ill, have a temperature or any other symptoms that accompany the pain
- are in the last 3 months of pregnancy (see also pregnancy and breast-feeding section).

This medicine is not recommended for use in children under 14 years of age.

Take special care with Diclofenac Diethylamine Gel

- Do not apply the gel to skin that has (i) a rash or eczema, (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.

- Avoid applying on large areas of skin and over prolonged period of time, unless under medical advice.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- Due to an increased possibility of side effects, take care if you are using any other medicine containing diclofenac or painkillers known as NSAIDs, such as aspirin or ibuprofen.
- A brace or wrap commonly used for injuries like sprains can be used, but do not use the gel under airtight (plastic) bandages.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- If you have or have ever had asthma speak to your doctor or pharmacist before using the gel.
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Diclofenac Diethylamine Gel

Please tell your doctor or pharmacist if you are taking, have recently taken, or want to start taking any other medicines, including those obtained without a medical prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

Diclofenac Diethylamine Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. This medicine should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Breast-feeding

This medicine should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Diclofenac Diethylamine Gel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time. Consult your doctor or pharmacist for further information if you are pregnant or breast-feeding.

Driving and using machines

Diclofenac Diethylamine Gel, when used as directed, is not expected to have any effect on your ability to drive or use machines.

Diclofenac Diethylamine 2.32% w/w Gel contains Propylene glycol (E1520)

This medicine contains 54 mg propylene glycol in 1 g of gel.

Diclofenac Diethylamine 2.32% w/w Gel contains Butylhydroxytoluene (E321)

Butylhydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Diclofenac Diethylamine 2.32% w/w Gel contains fragrances

This medicine contains fragrance with benzyl alcohol (0.15 mg/g, E1519), citral, citronellol, coumarin, eugenol, farnesol, geraniol, d-limonene and linalool which may cause allergic reactions. In addition, benzyl alcohol may cause mild local irritation.

3. How to use Diclofenac Diethylamine 2.32% w/w Gel

Always use this medicine exactly as your doctor has told you.

The gel is only for use on your skin. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.

Do not put Diclofenac Diethylamine Gel in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.

1. Before using for the first time, open as follows:
  - a. Unscrew the cap from the tube. To open the safety seal of the tube, reverse the cap and engage with the nozzle. Do not use scissors or other sharp objects!
  - b. Twist and remove the plastic seal from the tube. Do not use if the seal is broken.
2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin. The amount needed will vary depending upon the size of the painful or swollen area; an amount ranging in size from a 1 penny to a 2 pence piece will usually be sufficient (2-4g). You may notice a slight cooling effect when you rub the gel in. Only use the smallest amount of this medicine needed to relieve your pain but never use more than 8g per day and 56g in one week.
3. Unless the hands are the site being treated, wash your hands after rubbing in the gel, to avoid accidental contact with the mouth and eyes (see section 2).
4. **Do not** use this medicine for more than 14 days unless longer treatment is recommended by a doctor.

If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor.

In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

**If you use more Diclofenac Diethylamine Gel than you should**

An overdose is unlikely to happen if you use more Diclofenac Diethylamine Gel than you should, because the absorption into the blood stream is low when used on the skin. If the recommended dose is significantly exceeded when used on the skin, the gel should be removed and washed off with water.

If you or a child accidentally swallows this medicine, contact your doctor or accident and emergency department immediately.

**If you forget to use Diclofenac Diethylamine Gel**

If you miss your application of this medicine at the correct time, apply it when you remember and then carry on as normal. Do not apply a double quantity to make up for the forgotten application.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Diclofenac Diethylamine Gel can cause side effects, although not everybody gets them.

**Some rare and very rare side effects may be serious.**

If you experience any of the following signs of allergy, **stop** using this medicine and tell a doctor or pharmacist immediately.

- Skin rash with blisters; hives (may affect up to 1 in 1,000 people).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (may affect up to 1 in 10,000 people).
- Swelling of the face, lips, tongue or throat (may affect up to 1 in 10,000 people).

Other side effects are possible:

**Common side effects** (may affect up to 1 in 10 people):

- Skin rash, itching, reddening, eczema, dermatitis (inflammation of the skin) including contact dermatitis.

**Very rare side effects** (may affect up to 1 in 10,000 people)

- Pustular rash, hypersensitivity reactions (including hives), sensitivity to light with appearance of skin reactions after exposition to sunlight (possible signs are sunburn with itching, swelling and blistering).

**Not known side effects** (frequency cannot be estimated from the available data).

- Local application site irritation, peeling of the skin, skin discolouration, burning sensation at the application site, dry skin.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Diclofenac Diethylamine 2.32% w/w Gel**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original tube in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Please, do not apply the ointment shortly before taking a shower or bath. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Diclofenac Diethylamine 2.32% w/w Gel contains**

- The active substance is diclofenac.
- 1 g contains 23.2 mg diclofenac diethylamine corresponding to 20 mg diclofenac sodium
- The other ingredients are isopropyl alcohol, propylene glycol (E1520), cocoyl caprylocaprate, liquid paraffin, carbomer, macrogol cetostearyl ether, diethylamine, oleic acid (E570), butylhydroxytoluene (E321), fragrance (containing citronellol, geraniol, benzyl alcohol (E1519), linalool, limonene, citral, farnesol, coumarin, eugenol), purified water.

**What Diclofenac Diethylamine 2.32% w/w Gel looks like and contents of the pack**

White to almost white, homogeneous gel, packed in aluminium laminated tubes, closed with PE seal and PP screw caps, available in pack sizes: 30g, 50g, 60g, 100g, 150g, 180g per tube.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

**Manufacturer:**

Merckle GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany

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